Ref: 06.05.24E 004

PGEU/ EUROPHARM FORUM AND FIP SUBMISSION

Commission consultation "An assessment of the Community System of Pharmacovigilance"

PGEU GPUE Groupement Pharmaceutique de l'Union Européenne
Pharmaceutical Group of the European Union

EUROPHARM FORUM

INTERNATIONAL PHARMACEUTICAL FEDERATION FIP

Introduction

The ***Pharmaceutical Group of the European Union*** (PGEU) – www.pgeu.org – represents the community pharmacists of 29 European Countries. The Members of the PGEU are the professional bodies and pharmacists' associations in EU Members States, EU candidate countries and EEA Member States.

PGEU objective is to promote the role of the pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision making process. In addition PGEU provides its' members with an ideal platform to facilitate exchange of information, collecting and disseminating best practices. PGEU also encourages its members to further develop new projects aiming at anticipating and responding to society's needs, in the brooder context of Public Health.

Thus, PGEU has a leading and motivational role in awareness raising and actions' coordination within its members.

EuroPharm Forum – www.euro.who.int/europharm – is a joint network of national pharmaceutical associations and the World Health Organization Regional Office for Europe with the mission to improve health in Europe according to priorities set by WHO, and effected through dialogue and cooperation between the national associations and WHO.

The Forum seeks to strengthen all aspects of the pharmacist contribution to health in Europe and all the professional programmes are directed primarily towards health promotion and improved management of chronic illness. The programme work includes developing best pharmacy practices intended for adaptation to specific conditions in the member countries and to equip and support community pharmacists in their work. An additional element in the work is the documentation of the impact of the pharmacists' involvement.

International Pharmaceutical Federation (FIP) – www.fip.org – Is a world-wide federation of national pharmaceutical (professional and scientific) associations, with a mission to represent and serve pharmacy and pharmaceutical sciences around the globe. Through its member associations, FIP connects, represents and serves more than a million pharmacists and pharmaceutical scientists around the world.

The three organisations welcome the Commission consultation on the assessment of the Community Pharmacovigilance System as we consider this to be an important contribution in the overall framework of public health.

Community pharmacists throughout Europe are committed to making a major contribution to improving public health. This includes seeking to ensure that people derive maximum therapeutic benefit, and encounter minimum untoward side effects, from medicines provided from their pharmacies. They can therefore make an important contribution in the field of pharmacovigilance.

Comments

Our organisations do not wish to comment on the parts of the report dealing, for example, with weaknesses in pharmacovigilance systems in some Member States arising from wide variations in levels of staffing and technical resources or difficulties in accessing external expertise. These are important matters but they can only properly be dealt with by the Member States, in co-operation with the European Medicines Agency (EMEA) and the Commission. We wish to address topics of specific relevance and importance to community pharmacists and their relationship with patients and other users of pharmacy services.

The legal framework

The recent changes to the pharmacovigilance provisions in the EU pharmaceuticals legislation are welcomed. As the report makes clear, however, it is important that the opportunity the new legislation provides to strengthen the impact of tackling safety issues more proactively, should be used extensively.

The development of the Eudravigilance database should be a priority as should the monitoring of the effectiveness of companies' pharmacovigilance and, where appropriate, risk management systems. There should also be an emphasis on the importance of the diligent preparation and assessment of Periodic Safety Update Reports. This will be valuable in maintaining public confidence in the pharmacovigilance system.

The report, and the Commission's Consultation Paper, refer to the complications that arise from the fact that, within the EU pharmacovigilance system, functions, responsibilities and accountability are shared between the competent authorities in the Member States (NCAs) and the (EMEA). The division of responsibilities depends upon whether a medicine is authorised for marketing under the centralised or non-centralised procedure.

This, however, has no immediate relevance to those whom a pharmacovigilance system must be designed to protect – those who take or use a medicine for which a marketing authorisation has been granted under either procedure. Individuals are unlikely to know, or to care about, which procedure has been involved. Their concern will be to have confidence that medicines authorised for marketing in their country have met the required standards for safety, quality and efficacy and that an effective system is in place for continuous monitoring of quality and safety and for appropriate and prompt action to be taken if necessary to protect their health and safety.

As the EMEA's "Roadmap to 2010" made clear, pharmacovigilance must be pursued "throughout the lifecycle of a medicinal product …. to further strengthen public health protection." Nowadays, the later phase of the lifecycle of a medicinal product – comprehending the phase when the medicine is authorised to be marketed – may range from one used only in a hospital setting and perhaps to be prescribed only by specialists, to one that then becomes a "normal" prescription–only medicine for use in general medical practice, then becomes a medicine available for supply at a pharmacy by or under the supervision of a pharmacist and finally in some Member States, unfortunately in the opinion of our organisations, becomes available for sale outside pharmacies. At each stage, a larger population than previously is exposed to the effects of a medicinal substance and new adverse effects, not seen at an earlier stage, may occur.

It is important keeping in mind that medicines sold without prescription also can cause adverse drug reactions. Information about this risk must be provided on the package and the public should be made aware of the possibility for reporting any adverse drug reaction to their doctor or pharmacist. At the pharmacy, the focus of individuals is on their medicines, both those obtained against prescriptions and those used for responsible self-medication. And in the case of generic medicines, only the pharmacy can identify the actual product supplied.

In addition, we consider that special attention should be directed at pharmacovigilance for patient groups that are not routinely involved in clinical trials, for ethical and/or practical reasons (e.g.: pregnant women, children, elderly people and people using many drugs simultaneously). More research should be targeted to enable monitoring side effects and interactions for these groups. This could not only avoid unnecessary adverse events, but also prevent worries and concerns

about medicines that would have been discovered to be safe for these groups early on after marketing.

How community pharmacists can help through formal involvement in pharmacovigilance systems

Community pharmacies are recognised by members of the public as a vital, integral part of the health services in their country. They are also known to be conveniently accessible places where sound, objective advice on health issues can be obtained[1], from a knowledgeable health professional, in an informal environment in which they feel relaxed, without the need to make an appointment. In brief, pharmacies are obvious centres in every community for the effective transmission of messages designed to encourage healthy lifestyles and ensure the population about the safety, quality and efficacy of the medicines they use. Therefore, spontaneous reporting of suspected adverse reactions to medicines by pharmacists will remain an important element of effective pharmacovigilance.

Within the scope of Directive 85/432, the pharmacist is the specialist in the field of medicinal products, for veterinary as well as for human use, and therefore trained within this/her undergraduate studies to have a comprehensive understanding of the importance and impact of pharmacovigilance. The EMEA recognises that underreporting continues to be a problem. Our organisations, its members and pharmacist educational establishments are already committed to raising pharmacovigilance awareness on the part of practising pharmacists. There needs, however, to be better mechanisms for feedback, through professional journals and bulletins from national competent authorities on observations submitted by health professionals and, where appropriate, on action taken as a result. This will encourage others to be active in this area.

In addition, we consider that it is particularly important to continuously develop simplified and user friendly reporting systems that can be easily used in daily practice by health professionals.

Furthermore, the network of pharmacies could also be more involved in the collection of data needed to complement the "routine data" (spontaneous reports coming from healthcare professionals or marketing authorisation holders), especially on data combining medicines exposure and outcomes, including adverse drug reactions. Pharmacies are not only highly accessible throughout national territories, but also are already highly digitalized and could play and important role in this area. Additionally, pharmacists, through the network of pharmacies, act as a crossing point of information, linking different information coming from specialists, GPs and patient's self-medication. Therefore improving pharmacists' access to electronic patient records in what specifically concerns medication, in line with data protection authorities' requisites, could also be considered in order to better identify possible adverse reactions. In a moment when the Commission is highly investing in developing eHealth solutions, we would like to call the attention to this important aspect and underline the benefits that could arise from incorporating the pharmacovigilance system enhancement as an objective of such development.

It is important too that the EMEA should take the lead in raising the awareness of the public of pharmacovigilance as a public health issue. We consider that all patient information leaflets issued with medicines should encourage users to discuss any perceived undesirable side effect with their doctor or pharmacist.

The Report refers to collaboration with healthcare professionals, both as sources of data and as targets for effective communication. There appears, however, to be an emphasis on physicians in this regard. In some Member States community pharmacists are included formally in the system for reporting suspected adverse reactions to medicines. This is logical since people are likely to discuss, with their pharmacist, any problems they are encountering with a prescription-only medicine, perhaps when collecting a repeat supply, or with a previously purchased non-prescription medicine. Such discussions should become even more frequent if people are

[1] Several European wide and national surveys show that pharmacists are highly trusted for their professional services (i.e. Reader Digest "Most trusted Professional services, 2005"). Moreover, the Council of Europe Resolution ResAP(2001)2 concerning the pharmacist's role in the framework of health security recognizes that pharmacists provide added value to the healthcare system both through their scientific and pharmaceutical expertise and in term of ethics.

encouraged, by national competent authorities and by wording on all patient information leaflets for medicines, to become more involved in the pharmacovigilance system, by reporting any perceived adverse reaction to their doctor or pharmacist. When individuals report in this way to a community pharmacist, they will expect the pharmacist, in appropriate circumstances, to be in a position to report the concern formally to the relevant competent authority, within their country's pharmacovigilance system.

Unfortunately, community pharmacists are not systematically included in pharmacovigilance procedures in some Member States at present. In our opinion, this is a weakness.

We consider that the Commission and the EMEA should promote with the national regulatory authorities in those Member States where community pharmacists are not currently included in the pharmacovigilance system, the advantages of including them.

In the past, there has sometimes been resistance on the part of other health professionals to the inclusion of pharmacists, on grounds that have been shown to have no sound foundation when pharmacists are included in a properly structured system. Any such resistance should not be permitted to weaken a system which must have, as its first priority, the protection of the health and safety of European citizens.

Improving communication with health professionals and patients and the public

Under the EU pharmaceuticals legislation, the provision of pharmacovigilance data and information by the competent authorities to stakeholders (including patients) is a new requirement.

Experience in some Member States has demonstrated, all too often, the difficulty of providing information relating to action being taken as a result of pharmacovigilance, within a timetable, and in a manner, that does not lead to unnecessary concerns for patients.

The objective should be to seek to ensure that the relevant information is in the hands of health professionals before it is the subject of reports in the public media that often raise unnecessary alarm. Health professionals will then be in a position to advise on action to be taken and, in most cases, to reassure people. In virtually every case, the advice from the competent authority will be that people should seek further advice from their doctor or pharmacist. It is very frustrating if, when that advice is sought, the health professional has no more information than can be extracted from reports in the public media, which may or may not be accurate or complete.

We recognise that this objective may sometimes be difficult to achieve but in most cases it should be possible through a procedure agreed between the competent authority and the professional bodies representing healthcare professionals.

Moreover, communication between health professionals could also be targeted for enhancing the pharmacovigilance system. A concrete example is the case of generic substitution. It is important to stress that if a doctor is reporting an adverse drug reaction he/she could consult the community pharmacist to get information about possible substitution. On the other hand, and as it already happens in some countries, the community pharmacist is requested to inform the doctor about substitution. Such exchange of information would certainly contribute for improving pharmacovigilance goals.

In addition, it is important to underline the importance of having well trained and qualified professionals within the National Pharmacovigilance Authorities who could easily guide and exchange information with the practicing professionals dealing with spontaneous reporting and collection of other additional data.

On a separate point, we understood from a comment made by the Executive Director of the EMEA last year that although in some Member States, important information can be conveyed to health professionals within 24 hours, this can take up to 14 days in others. Our member associations have regular contact with the community pharmacies in the great majority of European countries, and have in many cases already implemented electronic decision support systems that could be used to communicate alerts and other relevant messages to pharmacists. With adequate support, we believe that we could develop a dissemination strategy, via these associations, to ensure that

important information reaches these pharmacies in the shortest possible time. We would welcome the opportunity to explore possible collaboration in this area.

Conclusions

As indicated in this submission, we consider that community pharmacies have an important role to play within the Community Pharmacovigilance System. The expertise of pharmacists and the existing network of pharmacies throughout national territories have long been available and should therefore be fully utilised.

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